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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,838	12/08/2000	Robert C. Fletcher	P-5093	3010

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EXAMINER	
CHIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/732,838	FLETCHER ET AL.	
	Examiner	Art Unit	
	Chris Chin	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group III – claims 47-56 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-46 have been cancelled.

Claim Rejections - 35 USC § 112

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is vague. In line 2, the recitation of "(2)-enzyme" is not clear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 47-51 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschfeld in view of Ueda et al.

Hirschfeld (U.S. Patent 4,514,508) discloses a method for the detection of multiple antigens or antibodies in a sample. The method utilizes a microtiter plate having a number of wells that do not communicate with each other. Each of the wells contains a different antibody (or antigen) that is specific for each of the antigens (or antibodies) that are to be detected in the sample (see col. 4, lines 6-60). The method can be a solid phase enzyme linked immunosorbent assay (see col. 4, lines 65-68). A test kit is also disclosed comprising (a) a solid phase matrix (i.e. a microtiter plate) having either antigens or haptens, antibodies or portions thereof, or a combination of antigens, haptens, antibodies, and portions of antibodies attached in identifiable positions of the solid phase matrix; (b) a detection compound; and (c) labeled antibody or portions thereof directed against the detection compound. The kit may optionally contain buffer, ovalbumin, and such other reagents as may be necessary to allow the chemical and biological reactions to take place (see col. 5, lines 3-16). Detection of antigen-antibody complexes is done via the use of complement (Clq) and enzyme labeled anti-Clq IgG. For a peroxidase label, 3-amino-9-ethyl carbazole (i.e. a

chromogen) is the substrate (see cols. 5-6). The disclosed method can be used in the analysis of body fluids for the presence of pathogenic microbes (see col. 7, lines 40-50).

Hirschfeld differs from the instant invention in failing to teach a kit for the detection of Influenza A and Influenza B using anti-Influenza A monoclonal murine antibody-enzyme conjugates and anti-Influenza B monoclonal murine antibody-enzyme conjugates.

Ueda et al (Journal of Clinical Microbiology, vol. 36(2), Feb. 1998, pp 340-344) discloses 2 murine monoclonal antibodies specific for Influenza A (C179) and B (F49). The 2 monoclonal antibodies were used in an immunoprecipitation assay to detect Influenza A and B – see pages 340-341.

It would have been obvious to one of ordinary skill in the art to use the Influenza A and Influenza B specific murine monoclonal antibodies of Ueda et al in the kit of Hirschfeld because the choice of analyte dictates the appropriate reagents that should be used. Hirschfeld broadly teaches the detection of pathogenic microbes. Thus it would be obvious to use the appropriate antibodies for the specific pathogenic microbes, i.e. Influenza A and B, that are to be detected. With respect to claims 49 and 50, it also would have been obvious to substitute the anti-Clq IgG in Hirschfeld for the murine monoclonal antibodies of Ueda because they would obviate the need for the use of Clq and they would provide for a more sensitive assay. Monoclonal antibodies are well known for their specificity and thus be more reliable in attaching a label on the Influenza A or B for detection purposes.

Claims 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschfeld in view of Ueda et al as applied to claims 47-51 and 54 above, and further in view of Bogart et al.

See above for the teachings of Hirschfeld and Ueda et al.

Hirschfeld and Ueda et al further differ from the instant invention in failing to teach including an extraction reagent, specifically a mucolytic agent.

Bogart et al (U.S. Patent 5,494,801) teaches the use of mucolytic agents to extract antigens from a body fluid. The mucolytic agent reduces or eliminates non-specific binding and should also increase the recovery of extracted antigens (see col. 10, lines 15-49).

It would have been obvious to one of ordinary skill in the art to include a mucolytic agent, as taught by Bogart et al, in the kit of Hirschfeld, as modified by Ueda et al, because the mucolytic agent provides the advantage of reducing or eliminating non-specific binding and should also increase the recovery of extracted antigens.

Claims 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschfeld in view of Ueda et al as applied to claims 47-51 and 54 above, and further in view of Nyez.

See above for the teachings of Hirschfeld and Ueda et al.

Hirschfeld and Ueda et al further differ from the instant invention in failing to teach the use of a stop reagent such as citric acid.

Nyez (U.S. Patent 5,279,935) discloses a solid phase assay for the detection of Influenza A. The assay uses citric acid to deactivate any endogenous alkaline phosphatase that may be present (see cols. 1-4).

It would have been obvious to one of ordinary skill in the art to include citric acid, as taught by Nyez, in the kit of Hirschfeld, as modified by Ueda et al, because the citric acid would provide the advantage of negating any adverse effects that may be caused by the presence of the endogenous alkaline phosphatase to the enzymatic detection process of Hirschfeld.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following U.S. Patents disclose methods and apparatus for the detection of Influenza A and/or B:

3,770,380; 4,299,916; 4,366,241; 4,391,904; 5,006,464; 5,126,276; 5,139,934; 5,571,667; and 6,235,464.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris Chin whose telephone number is 571-272-0815. The examiner can normally be reached on Monday-Thursday from 10:00 am to 7:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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cchin/Feb. 23, 2004

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641